

(43) *Wet dressings (excluding astringent active ingredients in paragraph (a)(18)(ii) of this section and skin protectant and astringent active ingredients in §§ 347.10 and 347.12 of this chapter).*

Aloe vera

Calcium polysulfide

Calcium thiosulfate

Oxyquinoline sulfate

Sodium propionate

Any other ingredient labeled with claims or directions for use as a wet dressing

(44) *Wound wash saline.*

Sodium chloride solution

Sterile sodium chloride solution

Any other ingredient labeled with claims or directions for use as wound wash saline

(45) *Urea.* Any product containing urea for any labeled claims.

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(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(52) of this section.

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(2) February 10, 1992, for products subject to paragraph (a)(20)(i) of this section.

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(52) [Date 180 days after date of publication of a final rule in the **Federal Register**], for products subject to paragraphs (a)(10)(viii), (a)(18)(vii), (a)(18)(viii), (a)(20)(iii), (a)(27)(iii), and (a)(30) through (a)(45) of this section.

Dated: June 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Notice No. 84; Re: Notice No. 68]

RIN 1513-AB26

Proposed Establishment of the Tulocay Viticultural Area (2006R-009P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau announces the withdrawal of its proposal to establish the Tulocay viticultural area in southern Napa County, California. We take this action because of questions regarding the actual name of the proposed viticultural area and to avoid the use of potentially misleading statements on wine labels.

DATES: The withdrawal of the proposal to establish the Tulocay viticultural area is effective on June 19, 2008.

FOR FURTHER INFORMATION CONTACT: N. A. Sutton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., 158, Petaluma, CA 94952; telephone 415-271-1254.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for petitions for the establishment of viticultural areas and contains the list of approved viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been recognized and defined in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps

consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to include—

- Evidence that the name of the viticultural area is locally and/or nationally known as referring to the area specified in the application;
- Historical or current evidence that the boundaries of the viticultural area are as specified in the application;
- Evidence relating to the geographical features (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;
- The specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (USGS) maps of the largest applicable scale; and
- A copy of the appropriate USGS map(s) with boundaries prominently marked.

Publication of Notice No. 68

On November 8, 2006, TTB published in the **Federal Register** (71 FR 65432), as Notice No. 68, a notice of proposed rulemaking to establish the “Tulocay” American viticultural area in southern Napa County, California. We undertook that action in response to a petition filed by Aaron Pott, a winemaker, and Marshall Newman of Newman Communications, on behalf of vintners and grape growers in the Tulocay region of Napa County, California. As explained in Notice No. 68, the proposed Tulocay viticultural area lies entirely within Napa County and also entirely within the existing Napa Valley viticultural area (27 CFR 9.23), which in turn is entirely within the existing, multi-county North Coast viticultural area (27 CFR 9.30). Notice No. 68 invited comments from the public on the proposal, and the comment period closed on January 8, 2007.

Comments Received in Response to Notice No. 68

TTB received 20 comments in response to Notice No. 68 during the comment period. Of those, 8 comments supported the petition and 12 comments requested that the proposed Tulocay

viticultural area's name be changed to "Coombsville," or "Coombsville District," while maintaining the proposed boundary line. After the close of the comment period, TTB received one comment supporting the petition and two comments opposing the establishment of the proposed Tulocay viticultural area.

Comments Fully in Support

The supportive commenters stated that the Tulocay region is a unique grape-growing region with different seasonal changes, climatic conditions, topography, soils, and growing season, as compared to the rest of the Napa Valley. Also, one supporting commenter explained that the Tulocay Land Grant is an important part of Napa Valley history. The Napa Valley Vintners Association, in a letter submitted after the close of the comment period, supported the establishment of the Tulocay viticultural area, explaining that its Appellation Committee reviewed the Tulocay viticultural area petition and found it to be comprehensive and deserving of endorsement.

Name Change Comments

Tom Farella, owner of a vineyard and winery located within the proposed Tulocay viticultural area, qualified his support for the proposed viticultural area's establishment by disagreeing with the "Tulocay" name and stating a preference for the name "Coombsville." He stated that Coombsville is the common neighborhood description used for real estate, in references to the area by the main local newspaper (the Napa Register), and by the greater local public. Mr. Farella also noted that a recent article in Wine and Spirits magazine referred to the area as Coombsville, and that the Coombsville name "has been cited in wine books and publications for years." He added that the petitioners chose to ignore use of the Coombsville name because they did not like its sound and that they would not discuss the matter when he brought the issue up during informal meetings. Finally, if TTB were to proceed with the name "Tulocay," he strongly endorsed the addition of "District" to the name in order to avoid confusion with the long-established "Tulocay" brand name used by Tulocay Winery. In this regard, he stated, "Our vineyard and winery are located at the very heart of the proposed viticultural area and I would be disinclined to add simply "Tulocay" to our label. I find that it would be very confusing for the consumer to see our brand and Bill Cadman's Tulocay brand on the same label."

A comment from Michael L. Turner, also expressed a preference for the name "Coombsville" or "Coombsville District" and included historical information about Nathan Coombs, an early American settler of Napa County regarded as the founder of the city of Napa. Mr. Coombs is memorialized by Coombs Street, located in downtown Napa to the west of the proposed viticultural area boundary line, and by Coombsville Road, which runs east to west through the southern part of the proposed viticultural area. Other commenters supporting the use of the "Coombsville" name echoed the comments of Mr. Farella and Mr. Turner regarding the use of the Coombsville name in southern Napa County and Nathan Coombs' role in the settlement of Napa County.

Comments From Tulocay Winery

After the close of the Notice No. 68 public comment period, TTB received a letter from Bill Cadman, the owner of Tulocay Winery, which is located on Coombsville Road in Napa. Noting that he has used the Tulocay brand name since his first vintage in 1975, Mr. Cadman strenuously objected to the establishment of the proposed Tulocay viticultural area since this would cause "inestimable economic damage" to a label and wine reputation that he has worked over 30 years to create. Mr. Cadman stated that he grows no grapes, but buys them from independent growers in Napa, Sonoma, Amador, and El Dorado Counties, California. Stating that his Tulocay brand Amador County Zinfandel wine vintages date from 1975 to the present, Mr. Cadman argued that if the proposed Tulocay viticultural area were approved, California State law would then prohibit production of his Tulocay brand name wines from grapes grown outside of Napa County. Mr. Cadman further stated that the State of California could seize and dispose of his Tulocay wines made from non-Napa County grapes and produced after January 1, 2001.

TTB was also contacted by Kristen Techel, attorney for Mr. Cadman, who submitted a memorandum that included additional information in support of Mr. Cadman's assertions. Ms. Techel explained that in August 2004, the California Supreme Court issued an opinion in *Bronco Wine Company v. Jolly*, 33 Cal. 4th 943 (2004), cert. denied, 544 U.S. 922 (2005), supporting section 25241 of the California Business & Professions Code (CB&PC), which allows the use of specified viticulturally significant names (that is, "Napa," or any viticultural area appellation of origin established under part 9 of the

TTB regulations and located entirely within Napa County, or any name similar to the foregoing that is likely to cause confusion as to the origin of the wine) only if at least 75 percent of the wine was derived from grapes grown in Napa County.

Ms. Techel further stated that the *Bronco* decision made it clear that the Federal grandfather clause (27 CFR 4.39(i)(2)) regarding the use of viticultural area names cannot be used to save Mr. Cadman's Tulocay brand labels which would be in conflict with section 25241 of the CB&PC (that is, Tulocay brand labels that are used on wines, more than 25 percent of which were created from grapes grown outside of Napa County). She asserted that if the Tulocay viticultural area were established by TTB, Tulocay Winery might have to destroy existing wines and stop production of its most popular wines. Ms. Techel then urged TTB to use extreme caution in granting viticultural area petitions within Napa because of the dire effects of this State law.

Ms. Techel also asserted that the Tulocay petition must be rejected because the area described in the petition is known as Coombsville. She stated that local residents most often refer to the area as Coombsville, that local real estate listings generally refer to Coombsville, and that the Napa County General Plan refers to the region within the proposed viticultural area as Coombsville. She also cited articles from the July 2001 issue of Wine Spectator ("Putting Coombsville on the Map for Napa Cabernet") and from the December 2006 issue of Wine & Spirits Magazine ("The Future of Napa Cabernet") as evidence that the area is known as Coombsville. She concluded that Coombsville is what the wine industry already calls this area.

Analysis of Comments

Name Dispute

The proposed Tulocay viticultural area petition and supporting documentation focused on the Tulocay name as used for a historical land grant, an in-use cemetery, and several other Napa County sites. The Tulocay viticultural area petitioners included an 1859 plat map that labels the area as "Tulocay Rancho," and an 1876 Napa County map which labeled the area as "Rancho Tulocay." Further, a publication, "The Past is Father of the Present, a Spanish California History and Family Legends 1737-1973," by Vivienne Juarez Rose, included the article "Days of Old on Rancho Tulocay," which features personal accounts of

several members of the Juarez family. However, evidence of the current use of "Tulocay" to refer to the proposed area is rather limited. The USGS 1980 photorevised Napa and the 1968 photorevised Mt. George quadrangle maps included with the petition show Tulocay Creek flowing through the proposed viticultural area, and two USGS topographic maps label the general region as "Tulocay." However, TTB conducted research through the on-line Geographic Names Information System (GNIS) maintained by the USGS, and for "Tulocay" there were only three references—the cemetery, a creek, and Tulocay Winery. Thus, other than the USGS maps with a reference to Tulocay, there is little evidence that the area in question is currently locally and/or nationally known as "Tulocay."

The comments in support of "Coombsville" and "Coombsville District" include historical references to Nathan Coombs, as well as fairly recent references to the region as "Coombsville." These current references include references in Napa County documents as well as specific references to the area known as "Coombsville" appearing in wine related publications. However, TTB's own review of maps of the general area (the Napa Valley Communities map, published in March of 1999 by the American Automobile Association, and the USGS 1980 photorevised Napa and 1968 photorevised Mt. George quadrangle maps) revealed the name "Coombsville" only in connection with "Coombsville Road," which runs east-west in the southern portion of the proposed Tulocay viticultural area. TTB's research through GNIS found no hits for "Coombsville" or "Coombsville District" anywhere in California.

In sum, the comments received on changing the proposed Tulocay viticultural area's name to "Coombsville" or "Coombsville District" had some current evidence of the use of the name "Coombsville" but lacked sufficient substantiating evidence in the form of map references or GNIS hits to support the use of either of those names for the proposed viticultural area. Further, though the commenters suggest "Coombsville" or "Coombsville District" would be their preferred name for the proposed viticultural area, it should be noted that TTB has not received a petition proposing the establishment of a viticultural area named "Coombsville" or "Coombsville District"; the petition received by TTB proposed the name "Tulocay" as the name of the viticultural area.

In regard to Mr. Farella's comment that the name "Tulocay District" should be considered, neither the current Tulocay viticultural area petition nor Mr. Farella's letter contained any documentation or other substantiating evidence in favor of the name "Tulocay District." Further TTB found no hits for "Tulocay District" through GNIS.

After careful consideration of all the name evidence, TTB believes that the limited documentation evidencing that the area in question is currently known as Tulocay and the significant number of commenters in favor of the names "Coombsville" and "Coombsville District," along with the documentation they included with their comments, cast doubt on the advisability of recognizing "Tulocay" standing alone as the name of the petitioned-for viticultural area. In particular, the petition name evidence and the commenters' evidence in support of Coombsville and Coombsville District, taken together, demonstrate a lack of unity among the region's industry members as to what the name of the petitioned-for viticultural area is locally and/or nationally known as, thus drawing into question whether there is, in fact, a viticultural area known as "Tulocay" that TTB should recognize in its regulations.

Effect on Tulocay Winery

Under the TTB regulations, for a wine to be labeled with a viticultural area name or with a brand name that includes a viticultural area name or other term identified as being viticulturally significant in part 9 of the TTB regulations, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name or other term, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with the viticultural area name or other viticulturally significant term and that name or term appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label.

The TTB regulations in 27 CFR 4.39(i)(2) contain a "grandfather" clause exception to the 85 percent rule described above. Under this exception, for brand names used in existing certificates of label approval issued prior to July 7, 1986, the labels may continue to be used even though the brand name includes a viticultural area name or other term of viticultural significance and the wine does not meet the 85 percent rule, provided that:

- The wine is labeled with an appellation of origin as specified in § 4.39(i)(2)(ii); or
- The wine is labeled with some other statement that TTB finds "sufficient to dispel the impression that the geographic area suggested by the brand name is indicative of the origin of the wine" (§ 4.39(i)(2)(iii)).

It is clear that Mr. Cadman's Tulocay wine labels would be "grandfathered" under the TTB regulations if the proposed Tulocay viticultural area were established, and, accordingly, he could continue to use those grandfathered "Tulocay Winery" labels for TTB purposes provided that the labels meet the requirements of § 4.39(i)(2)(ii) or (iii).

However, based on the terms of section 25241 of the CB&PC and the California State Supreme Court's ruling in the *Bronco* case that the provisions of the California statute are not preempted by the § 4.39(i) grandfather provision, it is clear that the TTB regulatory provisions would afford no effective label use protection to Tulocay Winery once the proposed Tulocay viticultural area were established. This is because under section 25241(c)(2) of the CB&PC, "Tulocay" would be a name of viticultural significance, thus allowing Mr. Cadman to continue to use the name of his winery on his labels only if his wine qualifies for use of the Napa County appellation of origin under Federal regulations (that is, at least 75 percent of the wine must be derived from grapes grown within Napa County). Under section 25241 of the CB&PC, operations in contravention of that provision could result in suspension or revocation of a license and seizure and disposal of the wine by the State of California.

TTB Finding

After careful consideration TTB has determined that it would not be appropriate to proceed with the establishment of the proposed Tulocay American viticultural area for the following reasons:

- The comments submitted, and the evidence and other information available, raise a substantial question as to whether there is a sufficient basis to conclude that the geographical area described in the petition is locally or nationally known as "Tulocay." While evidence suggesting the name "Coombsville" is a factor in this regard, the evidence currently available would not, standing alone, support the establishment of a viticultural area under the names "Coombsville" or "Coombsville District." Moreover, the evidence does not support the name

“Tulocay District,” and currently there is no petition requesting the establishment of a viticultural area in the subject area using a variation of Tulocay, such as Tulocay District, or any other name, such as Coombsville or Coombsville District. It is noted that these findings do not preclude future consideration of a petition, supported by sufficient name evidence, proposing the establishment of a viticultural area in the subject area using a name other than “Tulocay.”

- Consumer confusion could ensue regarding the identity and quality of wines bearing the term “Tulocay” if that term, which for more than 30 years has been identified with wines produced by Tulocay Winery from grapes grown in multiple California counties, were suddenly to disappear as a brand name of Tulocay Winery products and be used on labels for wines produced by other wineries primarily from grapes grown within a small portion of Napa County. Such consumer confusion resulting from the approval of the proposed Tulocay AVA is contrary to the purpose of the FAA Act.

For the reasons stated above, the proposal to establish the Tulocay viticultural area is withdrawn.

Signed: March 17, 2008.

John J. Manfreda,
Administrator.

Approved: June 13, 2008.

Timothy E. Skud,
Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

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DEPARTMENT OF JUSTICE

28 CFR Part 20

[Docket No. FBI 114]

RIN 1110-AA26

FBI Criminal Justice Information Services Division User Fees

AGENCY: Federal Bureau of Investigation (FBI), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The FBI is authorized to establish and collect fees for providing fingerprint-based and name-based Criminal History Record Information (CHRI) checks and other identification services submitted by authorized users for noncriminal justice purposes including employment and licensing. The FBI may set such fees at a level to include an amount to establish a fund to defray expenses for the automation of

fingerprint identification and criminal justice information services and associated costs. The proposed rule explains the methodology used to calculate the revised fees, provides the proposed fee schedule, and advises that future fee adjustments will be made by notice published in the **Federal Register**. After public comment, a final rule and notice of the final fee schedule will be published concurrently in the **Federal Register**.

DATES: Written comments must be received on or before August 18, 2008.

ADDRESSES: You may submit comments, identified by Docket No. FBI 114, by either of the following methods:

- *Federal Regulations Web site:* You may review this regulation on <http://www.Regulations.gov> and use the comment form for this regulation to submit your comments. You must include Docket No. FBI 114 in the subject box of your message.

- *Mail:* You may use the U.S. Postal Service or other commercial delivery services to submit written comments to the FBI Criminal Justice Information Services Division, 1000 Custer Hollow Road, Module E-3, Clarksburg, West Virginia 26306, Attention: Christopher L. Enourato. To ensure proper handling, please reference Docket No. FBI 114 in your comment. When submitting written comments, please allow for delivery time plus at least two days for internal mail security scanning and delivery.

FOR FURTHER INFORMATION CONTACT:

Christopher L. Enourato, FBI, Criminal Justice Information Services Division, 1000 Custer Hollow Road, Module E-3, Clarksburg, West Virginia 26306, telephone number 304-625-2910.

SUPPLEMENTARY INFORMATION:

- Posting of Public Comments
- Background
- Fee Calculation
- Revised Fee Schedule
- Administrative
- Regulatory Certifications

I. Posting of Public Comments

Please note that all comments on the proposed rule are considered part of the public record and made available for public inspection online at <http://www.Regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase “PERSONAL IDENTIFYING

INFORMATION” in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.Regulations.gov>.

Personal identifying information identified and located as set forth above will be placed in the agency’s public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency’s public docket file in person by appointment, please see the “For Additional Information” paragraph.

II. Background

For the purposes of this discussion, the FBI user fees are classified according to the FBI division that provides the check in question: the Records Management Division (RMD) or the Criminal Justice Information Services (CJIS) Division. The proposed rule implements the FBI’s statutory authority to establish and collect fees for noncriminal justice fingerprint-based and name-based CHRI checks and other identification services performed by the CJIS Division. Fees for name checks performed by RMD will be the subject of a separate rulemaking. Further, under 28 CFR 16.33, the FBI is authorized to collect a fee for the production of an FBI identification record in response to a written request by the subject of the record; adjustments to that fee will be set out in a third rulemaking.

The proposed rule explains the methodology used to calculate the FBI’s revised fees, provides a proposed fee schedule, and advises that future fee adjustments will be made by notice published in the **Federal Register**. After public comment, a final rule and notice of the final fee schedule will be published concurrently in the **Federal Register**. The rule will be published at 28 CFR Part 20.